DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 6, 2014

Syneron Medical Ltd.
c/o Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K141708
Trade/Device Name: Syneron UltraShape System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV
Dated: September 12, 2014
Received: September 12, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.06 08:36:38 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K141708

Device Name

UltraShape System

Indications for Use *(Describe)*

The UltraShape System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K141708

510(k) SUMMARY

Syneron Medical Ltd.'s UltraShape System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Philadelphia, PA 19103
Phone: 267 675 4600
Facsimile: 267 675 4601

Date Prepared: October 2, 2014

Name of Device

Syneron UltraShape System

Common or Usual Name

Focused Ultrasound Stimulator System for Aesthetic Use

Classification

Focused Ultrasound Stimulator System for Aesthetic Use

21 CFR 878.4590, Class II, product code OHV

Predicate Devices

Syneron Contour I V3.1 (K133238)

Intended Use / Indications for Use

The UltraShape System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference.

Device Description

The UltraShape System is comprised of multiple components, including the control unit and two ultrasonic transducers. The UltraShape System selectively targets subcutaneous

adipose tissue via focused ultrasound for the purpose of non-invasive aesthetic body contouring. The transducer is an electro-mechanical device that converts an electrical signal into mechanical (acoustical) energy. The operating parameters of the UltraShape System achieve selective disruption of adipose tissue without damaging neighboring tissues such as blood vessels, nerves, or muscle.

The purpose of this submission is to increase acoustic intensity and to add an additional smaller ultrasound transducer.

Technological Characteristics

The UltraShape System is comprised of the system console, including the computer, and two ultrasonic transducers. The transducers deliver the focused ultrasound energy beam to the targeted treatment area, and real-time optical and acoustic feedback (optional) on the treatment is provided via the tracking and guidance system. The transducers functionality is based on the piezoelectric effect implemented with the ceramic element.

Performance Data

The following nonclinical performance testing was conducted to support the substantial equivalence of the UltraShape System to the predicate device, consistent with FDA's "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use" (2011). In all instances, the UltraShape System functioned as intended.

- Biocompatibility testing in accordance with ISO 10993 for skin irritation, sensitization, cytotoxicity testing supported the biocompatibility of the patient-contacting components of the device.
- Beam profile testing demonstrated that the acoustic energy is delivered and concentrated in the desired target location, at a focal depth highly similar to that of the predicate device.
- Acoustic power testing demonstrated that the acoustic power of the transducers is highly predictable with low variability.
- In vitro acoustic and thermal measurements demonstrated the safety of non-targeted tissues both proximal and distal to the targeted region.
- Software verification and validation was performed, and demonstrated that the software performs as intended.
- Electrical safety (IEC 60601-1), electromagnetic compatibility (IEC 60601-1-2) and electromagnetic immunity testing was conducted and demonstrated the electrical safety of the device.
- In vivo testing in an animal model was performed which demonstrated the treatment effects of the UltraShape, and supported its safety and efficacy profile for the intended use.

In addition, clinical evaluation of the device in the intended population was performed in two, separate, prospective, single arm studies. The studies evaluated the safety and

effectiveness of the UltraShape in 102 enrolled subjects. The majority of the subjects were female with mean age of 44 years. After baseline screening, patients underwent three treatments each at two weeks apart, with follow-up visits at 2, 4, 8 and 12 weeks after the last treatment. The abdominal circumference reduction, weight, satisfaction and safety results were assessed for the study subjects throughout the study visits. The results demonstrated that at final follow-up, subjects achieved an average of -2.37 cm circumference reduction at the midline. Similar treatment results were observed at the measurement points 2 cm above and 2 cm below the midline. It should also be noted that very little weight change was observed in the study subjects overall, with an average weight change measuring less than 1% at 12 weeks (or longer term follow up) for all subjects. Midline circumference reduction results in the weight stable subjects (-2.18 cm) were very similar to the results observed in the overall population. Therefore, the subject device demonstrated substantially equivalent performance over time compared to the predicate in the overall study population and in the weight stable subgroup. Additional sensitivity analyses, including last observation carried forward (LOCF) and worst case analyses, continue to demonstrate the robust treatment effect of the UltraShape in abdominal circumference reduction. The safety profile of the UltraShape device was maintained through long term follow up; the only events in the studies were mild to moderate in severity and resolved within a few hours or days. In addition, the majority of subjects in the UltraShape studies reported overall satisfaction with treatment. An additional prospective clinical study assessed the device safety profile in 21 patients. Subjects underwent 3 treatment sessions each 2 weeks apart; follow-up visits occurred at 2, 4, 8 and 12 weeks after the last treatment visit. The study results further supported the safety profile of device treatment with only one minor event from which the patient completely recovered without the need for any intervention. Subjects reported minimal discomfort and overall satisfaction with the treatments.

Therefore, multiple clinical studies with the UltraShape device demonstrated successful circumference reduction and a positive safety profile, with no device related serious adverse events. Thus, the clinical studies support substantial equivalence to the predicate.

Substantial Equivalence

The UltraShape has the same indications for use, similar technological characteristics and the same principles of operation as its predicate device. The technological differences between the UltraShape and the Contour I V3.1 mainly consist of differences in acoustic intensity and the addition of a smaller transducer. Nonclinical and clinical studies of the UltraShape have demonstrated the safety and effectiveness profile of the UltraShape in the intended population. Thus, the UltraShape is substantially equivalent to the predicate device.

Conclusion

Syneron's UltraShape System is a Focused Ultrasound Stimulator System for Aesthetic Use Class II device that has been evaluated in nonclinical and clinical testing in accordance with FDA's Special Controls Guidance Document. Testing demonstrated that the device performs as intended. The UltraShape device is substantially equivalent to its predicate device (K133238).